

## **REMARKS**

New claims 58-74 are currently pending in this application. In the Preliminary Amendment submitted by Applicants and received by the United States Patent and Trademark Office on March 11, 2005 ("Preliminary Amendment"), Applicants cancelled from prosecution (without prejudice) claims 1-19 and 40-57. A copy of the Preliminary Amendment is attached along with a copy of the returned receipt postcard which contains the unaltered itemized listing of the Preliminary Amendment. In the Office Action mailed on January 18, 2007 ("Office Action"), claims 1-57 were rejected. Through this amendment, Applicants have cancelled claims 20-39 and reintroduced claims 40-56 as new claims 58-74. Therefore, only rejections made to claims 40-56 will be addressed. No new matter has been entered. Applicants respectfully request favorable consideration of the present application in light of the amendments to the claims and the following remarks.

### **I. Drawings**

The drawings were objected to on page 2 of the Office Action for not showing the "protector" feature of the invention in the specified claims. Applicants respectfully point out that replacement sheets are not needed because the following elements comprise the "protector" as used in the claims: cannula member 16 and lip member 22, as seen in Figure 1; retractor blade members 82, 84 and lip member 83, as seen in Figure 12. No changes to the drawings have been made and no new matter has been added.

### **II. Claim Rejections– 35 USC 102(e) - Reiley**

Claims 40-47, 49-52 (new claims 58-65, 67-70) were rejected under 35 USC 102(e) as being anticipated by US Patent No. 6,330,138 to Reiley et al ("Reiley"). Applicants respectfully traverse this rejection as set forth below.

In order for a reference to anticipate the present claimed invention under 35 U.S.C.

102(e), it must be shown that each and every element of the claim can be found in the reference. If it can be shown that one element of the claim is missing or not met by the cited reference, the rejection must be withdrawn as inappropriate.

New claim 58 recites a method for removing intervertebral disc material, comprising the steps of: creating a working channel from a patient's skin to a intervertebral disc space; inserting a brush member into said intervertebral disc space, said brush member having plurality of bristle members defining a capacity for carrying intervertebral disc material; manipulating said brush member within said intervertebral disc space to receive intervertebral disc material within said brush member; and removing said brush member from said intervertebral disc space.

The Reiley reference appears to be silent with regard to at least one element found in claim 58, such that the rejection for anticipation should be withdrawn. The Reiley reference does not disclose the element of claim 58 of the present invention that involves "inserting a brush member into said intervertebral disc space, said brush member having a plurality of bristle members defining a capacity for carrying intervertebral disc material."

First of all, the Reiley reference does not disclose a brush member having a plurality of bristle members defining a capacity for carrying intervertebral disc material, as found in Applicant's claim. Reiley discloses a brush member (referred to as a brush structure) with bristle members, however, the bristles do not define a capacity for carrying intervertebral disc material as stated in claim 58. The capacity of the bristle members to carry intervertebral disc material in Applicant's claim is important because it is the main means of extracting the intervertebral disc material. The brush member of Applicant's claim may be used to remove tissue as well as ablate or partially decorticate the surfaces of the adjacent vertebrae. No separate tools are needed to take the disc material out of the intervertebral disc space because the bristle members complete that function. This provides for an uncomplicated surgical process using only a single brush member.

By contrast, the Reiley reference utilizes a suction tube and rinsing fluid to remove the cancellous bone and form a cavity (column 9, line 54-67, and column 10, lines 1-3). The brush member of the Reiley reference is used only to cut the cancellous bone; it does not carry the cancellous bone out of the bone cavity. In order to extract the cancellous bone, a suction tube conveys rinsing liquid into the cavity and a vacuum aspirates the liquids and debris from the targeted tissue region. Thus, the method disclosed in the Reiley reference is more cumbersome than that of Applicant's claim. As a result, the method of Applicant's claim provides a quicker, more easily maneuverable procedure for surgeons to remove intervertebral disc material during surgery because the need for additional steps and tools is eliminated.

Secondly, the Reiley reference does not disclose inserting a brush member into an intervertebral disc space as found in Applicant's claim. Although Reiley discloses deployment and use of a brush tool in a vertebral body (column 9, lines 51-62), the deployment and use of a brush tool in an intervertebral disc is not mentioned. In fact, the main purpose of the Reiley reference is to form a bone cavity and remove cancellous bone, not intervertebral disc material as stated in Applicant's claim. Furthermore, though the Reiley reference states that its systems and methods can be adapted for any interior body region, nowhere does it clearly anticipate use in an intervertebral disc space or removal of intervertebral disc material. The only clear anticipation in the Reiley reference is for use inside a bone and removal of bone material.

Because Reiley fails to teach or disclose at least one claimed feature in the independent claim 58, Applicants respectfully submit that the rejection under 35 USC 102(b) should be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited. Since rejected claims 59-74 are all dependent upon independent claim 58, it follows that Applicants believe these claims to be in condition for allowance, and respectfully request a favorable indication in that regard.

**V. Claim Rejections - 35 USC 103(a)**

**A. Reiley**

Claims 40-47, 49-56 (new claims 58-65, 67-74) were rejected under 35 USC 103(a) as being unpatentable over US Patent No. 6,440,138 to Reiley. Applicants respectfully traverse this rejection as set forth below.

As noted above, Reiley failed to teach or disclose at least one feature found in independent claim 58. More specifically, Reiley does not appear to teach or contemplate inserting a brush member into an intervertebral disc space, and said brush member having a plurality of bristle members defining a capacity for carrying intervertebral disc material. Claims 59-75, being dependent upon claim 58, should be allowed for the reasons set forth above in support of the allowability of claim 58, as well as the additional features it contains.

Applicant respectfully requests that the rejection of claims 40-47, 49-56 (new claims 58-65, 67-74) be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

**B. Reiley in view of Worthen**

Claims 40-56 (new claims 58-74) were rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,440,138 to Reiley in view of US Patent No. 5,445,164 to Worthen et al ("Worthen"). Applicant respectfully traverses this rejection in light of the amendments to the claims and as set forth below.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art

reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

As noted above, Reiley failed to teach or disclose at least one feature found in independent claim 58. More specifically, Reiley does not appear to teach or contemplate inserting a brush member into an intervertebral disc space, and said brush member having a plurality of bristle members defining a capacity for carrying intervertebral disc material.

The Worthen reference does not cure the aforementioned deficiencies in what was fairly taught by Reiley. The Worthen reference discloses a sampling device for collecting tissue in a woman's cervix. The tissue sample is then sent to a laboratory to be screened for cervical cancer. More specifically, Worthen does not appear to teach or contemplate inserting a brush member into an intervertebral disc space for collecting intervertebral disc material. Although the Worthen reference discloses a circular brush and sponge system used to collect cervical tissue found in a woman's cervix (not to be confused with the cervical region of the spine), Worthen's cervical tissue sampling device does not apply to an intervertebral disc space. The sole application of the Worthen device is for collecting cervical tissue samples and vaginal cavity cells for laboratory testing. It allows women to do so in the privacy of their own home. The Worthen reference does not remotely disclose any other area or region in the body, besides the vagina, that the sampling device could be used. Therefore, given this void, one of ordinary skill in the art would not have been motivated to combine the Reiley and Worthen references, nor would such a combination have led them to arrive at the present invention as claimed.

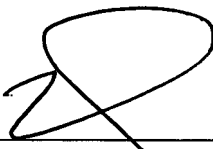
Claims 59-74, being dependent on claim 58, should be allowed for the reasons set forth above in support of allowability of claim 58, as well as the additional features it contains. Applicant respectfully requests that the rejection of claims 40-56 (new claims 59-74) be withdrawn in favor of an indication of allowance, which is hereby earnestly solicited.

## CONCLUSION

The foregoing amendment has been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,  
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